

**Maryland Board of Pharmacy
Public Board Meeting**

Agenda
Date: November 20, 2013

Name	Title	Present	Absent	Present	Absent
Board Committee					
Bradley-Baker, L.	Commissioner				
Finke, H.	Commissioner/Secretary				
Gavgani, M. Z.	Commissioner/Treasurer				
Israbian-Jamgochian, L.	Commissioner/President				
Jones, David H.	Commissioner				
Robinson, T.	Commissioner				
Rochester, C.	Commissioner				
Roy, S.	Commissioner				
Smith, J.	Commissioner				
St. Cyr, II, Z. W.	Commissioner				
Zagnit, B.	Commissioner				
Board Counsel					
Bethman, L.	Board Counsel				
Felter, B.	Staff Attorney				
Board Staff					
Naesea, L.	Executive Director				
Wu, Y.	Compliance Manager				
Waddell, L.	Licensing Manager				
Gaither, P.	Administration and Public Support Manager				
Jeffers, A.	Legislation/Regulations Manager				
	MIS Manager				

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)
I. Executive Committee Report(s)	<p>A.) L. Israbian-Jamgochian, Board President</p> <p>B.) H. Finke, Secretary</p>	<p><i>Members of the Board with a conflict of interest relating to any item on the agenda are advised to notify the Board at this time or when the issue is addressed in the agenda.</i></p> <ol style="list-style-type: none"> 1. Call to Order 2. Sign-in Introduction and of meeting attendees – <i>(Please indicate on sign-in sheet if you are requesting CE Units for attendance)</i> 3. Distribution of Agenda and packet materials 4. Review and approve October 16, 2013 Minutes <u>Draft Public Minutes 10-16-2013</u> 5. Lorena de Leon, Administrator, Office of Healthcare Quality. PowerPoint presentation regarding: “Maryland Background Check Program” <u>Maryland Background Check Program Presentation</u> 	
II. A. Executive Director Report	L. Naesea, Executive Director	<ol style="list-style-type: none"> 1. Operations Updates 2. Meetings Update <ul style="list-style-type: none"> • DHMH Regulatory Services Audit Meeting <u>DHMH Regulatory Services Discussion Notes</u> <u>BOP Response to DHMH Regulatory Services</u> 	

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B. Administration and Public Support (APS)	B. P. Gaither, APS Manager	1. Personnel Updates - Vacancies and Recruits 2. Contracts and Procurement	
C. MIS	J. Johnson, MIS Manager	1. MIS Update	
D. Licensing	L. Waddell, Licensing Manager	1. Licensing Unit Update 2. Monthly Statistics	
E. Compliance	Y. Wu, Compliance Manager	A. Monthly Statistics B. PEAC Update	
F. Legislation & Regulations	A. Jeffers, Legislation & Regulations Manager	<u>REGULATIONS: (5 Open Chapters)</u> 10.34.19 Sterile Pharmaceutical Compounding with 10.34.09 Fees Informal comments: Sterile Compounding Regulations 11.07.2013 MSHP Response Final 10-24-13etter to Anna D. Jeffers.Finaldoc Doherty Ch_397_hb0986T Pharm Cpdg Acc Bd 101613 Comment 10 34 19 Sterile Drug Prod Waiver 101513 St. Agnes Comment 10 34 19 Sterile Drug Prod Waiver 102413 Krug	

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		<p>DHMH Draft Comments on Sterile Drug Products and Waiver</p> <p>Draft 10 34 19 Sterile Drug Prod and Waiver 101113 Pharm Cpdg Accred Bd</p> <p>Draft 10 34 19 Sterile Drug Prod Waiver 101113 DTaylor</p> <p>Mel Rubin - MASA comment 103013</p> <p>Proposed Md Cmpdg Regs - JCB Laboratories 110813</p> <p>Question 10.34.19 Sam Georgiou 101713</p> <p>Sterile Compounding Regs - Informal Comments 10-25-13 MHA</p> <p>waiver_varianceapp2 JCB Labs</p> <p>Board approval requested for the following Board response:</p> <p>Draft Board Response to Informal Comments 111513</p> <p>Board approval requested for all the proposed revisions.</p> <p><u>Proposed COMAR 10.34.19 Sterile Compounding Preparations and Sterile Drug Products</u></p> <p><u>10.34.22 Licensing of Wholesale Prescription Drug or Device Distributors</u></p> <p>Board approval requested for revisions to this proposal that provide the Division of Drug Control with certain information and notification of closing of a wholesale distributor.</p>	

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		<p><u>10.34.22 and 10.34.37 to 16567 1 For 112013 Bd Mtg</u></p> <p><u>10.34.32 Pharmacist Administration of Vaccinations</u> Board approved proposal with a revisions to Regulation .08 Fees, on 092013. Submitted 092013 to DHMH Emergency for sign off and publication.</p> <p>Board of Nursing had concerns about the possible fees that could be charged to Medicaid recipients and suggested to leave the reimbursement rate for the administration of vaccinations stand for Medicaid reimbursed vaccinations and allow the maximum rate for all other vaccinations. The Practice Committee agreed and informed BoN that under the law no additional fees may be charged for vaccinations administered to Medicaid patients, so there would be no need to adjust the revisions to COMAR 10.34.32.08 Fees.</p> <p><u>10.34.33 Prescription Drug Repository Program</u> Proposal to be revised pursuant to federal regulations.</p> <p><u>10.13.01 Dispensing of Prescription Drugs by a Licensee</u></p> <p>The Board previously revised the proposal so that if a dispensing permit holder has more than one dispensing site, the DDC may not inspect the same site twice within the 5 year permit period.</p> <p>The Practice Committee recommended revising the proposal to require inspections of more than one dispensing site upon renewal.</p> <p>Board approval requested for:</p> <p><u>Draft Proposal 10.13.01 102313 Practice Recommendation</u></p> <p><u>MEETINGS:</u></p>	

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		<p>1) Workgroup on Pharmacy Benefits Managers and Specialty Drugs - October 29, 2013. The following groups presented at the October 29th Meeting:</p> <ul style="list-style-type: none"> • PBM Panel including Express Scripts and CVS Caremark • League of Life and Health Insurers • Medicaid MCO Survey presented by Marie Grant of DHMH • Maryland Insurance Administration <p>NEXT STEPS: At the end of the meeting, Chairman Hammen asked everyone to review the new Delaware law regarding PBMs and specialty drugs. He would like stakeholders to comment on the Delaware law and what stakeholders would like to see in legislation for the 2014 legislative session.</p> <p>DE Specialty Drugs</p> <p><u>Draft Board comment to HGO – PBMs and Specialty Drugs</u></p> <p>After he reviews all comments, he may circulate a proposed bill for 2014 for comment.</p> <p>2) Maryland Ambulatory Surgery Association – October 30, 2013 Presented with Mel Rubin explaining HB 986.</p> <p><u>HB 986 MASA Presentation ADJ</u></p> <p>3) Meeting with Senator Joan Carter Conway - November 14, 2013 regarding legislative initiative for the 2014 Legislative Session.</p>	

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		<p>4) Immunet Registry Study Workgroup - November 15, 2013 DHMH is studying the feasibility and desirability of requiring all Maryland healthcare providers who administer vaccinations to report those vaccinations to ImmuNet, the Maryland immunization registry, and would like the Board's input on these issues. Anna Jeffers attended the first meeting.</p> <p><u>ImmuNet Summary with Questions_Nov 2013</u></p> <p><u>ImmuNet Work Group Meeting_Nov 15 2013</u></p> <p><u>ImmuNet Workgroup Meeting Agenda_Nov 15 2013</u></p> <p><u>OTHER MATTERS:</u> 1) Legislative Reports: Board approval requested for:</p> <p>a) Prescription Drug Repository Annual Report</p> <p><u>DRAFT RxDrugRepReport to GenAssembly 100913</u></p> <p>b) Wholesale Distributor Annual Report</p> <p><u>DRAFT Report WholesaleDist Program 101313</u></p> <p><u>c) Report on the Implementation of Sterile Compounding Permits and Sterile Drug Product Waivers</u></p> <p><u>Draft Report HB 986 Sterile Comp 102913</u></p> <p>2) Re: Draft legislative proposal - mandated child abuse reporter training</p> <p><u>Draft Board Response – mandated child abuse reporter training</u></p>	

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III. Committee Reports A. Practice Committee	H. Finke, Chair,	<p><u>Inquiries:</u></p> <p>1) Edward Winiecki, Consumer</p> <p><u>Edward Winiecki</u></p> <p><u>Draft Bd Response - Meds from India</u></p> <p>2) Dr, Geoff Coleman, Montgomery Hospice/Palliative Medicine Consultants</p> <p><u>Nurses dispensing OTC to hospice patients</u></p> <p><u>Draft Bd Response - OTC meds delivered to hospice</u></p> <p>3) John Beckman, Beckman's Green Street Pharmacy</p> <p><u>Beckman's Pharmacy DTM question</u></p> <p><u>Draft Bd Response - DTM</u></p> <p>4) Roman Kaplan</p> <p><u>Sabbath dispensing - not on orig agenda</u></p> <p><u>Draft Bd Response - Sabbath Dispensing</u></p> <p>5) John Sullivan, Managing Partner, Marjo, LLC - NIH Grant proposal</p> <p><u>Specific Aims 10-16-2013</u></p> <p><u>Draft Bd Response - NIH grant concept</u></p>	

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B. Licensing Committee	L. Bradley-Baker, Chair	<p>1. Review of Pharmacist Applications:</p> <p>A. <u>Michelle Lee</u> - Would like an extension of application to take the MPJE. Licensing Committee recommendation is to approve extension until December 31, 2013 because of family medical concerns.;</p> <p>B. <u>Oluseyi Ogunyankin</u> - Would like waiver of reinstatement fees. Licensing Committee recommendation is to deny request and to inform pharmacist that he has to pay fees before he is reinstated; and</p> <p>C. <u>Robert Dunn</u> - Would like waiver of oral competency because there is not a Berlitz within 300 miles of home and have reached out to Berlitz to complete it online and haven't gotten a response. Licensing Committee recommendation is to deny the request and inform pharmacist that he has to take competency exam as well as pay reactivation fees as application is now expired.</p> <p>2. Review of Pharmacy Technician Applications: None</p> <p>3. Review of Distributor Applications: None</p> <p>4. Review of Pharmacy Applications: None</p> <p>5. Review of Pharmacy Tech. Training Programs: None</p> <p>6. New Business:</p> <p>A. <u>Walmart and Sam's Club Openings</u> - Would like clarification on a couple of questions regarding the opening of new locations. Licensing Committee recommendation is to inform company that as long as they have obtained MD permit, they are able to process valid prescriptions, citing appropriate regulations in the</p>	

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		<p>letter;.</p> <p>B. Rx Prep - Would like the Board to review their program and refer as a remediation program for referring those who have failed the NAPLEX repeatedly. Licensing Committee Recommendation is to inform company that the Board is not interested in endorsing any particular program but they are able to advertise their program in the state of MD; and</p> <p>C. Technician Training Program Clarification - Discussion of ASHP 2020 requirements that all technician training programs to have an experiential component. MD law prohibits programs that are not Board approved to complete experiential hours in MD licensed pharmacies. Licensing Committee recommendation is to plan to change regulations to include that MD will accept ASHP accredited programs to complete experiential hours in a MD approved pharmacy to obtain national certification.</p>	
C. Public Relations Committee	L. Bradley-Baker, Chair	<p>Public Relations Committee Update:</p> <ul style="list-style-type: none"> • Outgoing Board Commissioner Recognition Event; and • Script Your Future Baltimore Motivational Interviewing Session 	
D. Disciplinary	M, Gavgani, Chair	Disciplinary Committee Update:	

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		<p>1. Community Inspections-PDMP (please see attachment)</p> <p><u>Community Inspection Form-PDMP;</u></p> <p>2. Fines to pharmacists and pharmacy technicians for failure to notify the Board about the change of address.</p>	
E. Emergency Preparedness Task Force	L. Bradley-Baker, Acting Chair	<p>Emergency Preparedness Task Force Update:</p> <ul style="list-style-type: none"> • DHMH feedback on EPTF's role during September 2013 drill; • Recruitment of Pharmacy Volunteers for Emergency Preparedness; and • Expanded scope of EPTF. 	
IV. Other Business & FYI	L. Israbian-Jamgochian, Board President	None.	
V. Adjournment	L. Israbian-Jamgochian, Board President	<p>The Public Meeting was adjourned at _____.</p> <p>At _____ P.M. L. Israbian-Jamgochian convened a Closed Public Session to conduct a medical review of technician applications.</p> <p>C. The Closed Public Session was adjourned at _____ P.M. Immediately thereafter, L. Israbian-Jamgochian convened an Administrative Session for purposes of discussing confidential disciplinary cases. With the exception of cases requiring recusals, the Board members present at the Public Meeting continued to participate in the Administrative Session.</p>	

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